IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	)	Civil Action No. 4:21-cv-01058-P

JOINT STATUS REPORT

Pursuant to the Court's Order dated January 6, 2022 (Dkt. No. 35), the parties hereby submit the instant Joint Status Report ("JSR"). Consistent with this Court's Order of February 2, 2022 (Dkt. No. 56), and in the interim since the parties' last JSR, filed on December 24, 2022 (Dkt. No. 64), the U.S. Food and Drug Administration ("FDA") has made the following additional productions:

- A January 3, 2023 production consisting of 58,725 pages of responsive records;
- A February 1, 2023 production consisting of 56,874 pages of responsive records; and
- A March 1, 2023 production consisting of 13,492 pages of responsive records and FDA applied 41,508 of its banked pages to this production.

Pursuant to the February 2, 2022 Order, FDA may "bank" any pages produced in excess of its monthly quota, and, if FDA is unable to produce the full amount of pages required in a subsequent month, it can apply the banked pages toward its quota for that month. To date, FDA has 50,479 banked pages remaining. FDA expects to produce a minimum of 55,000 pages (or utilize its remaining banked pages to account for at least 55,000 pages) on or before April 3, 2023.

On December 22, 2022, Plaintiff asked FDA to provide an estimated remaining page count and/or estimated completion date of production. On December 23, 2022, FDA responded that it was not presently in a position to provide an estimated remaining page count or estimated completion date because it was still assessing the scope of records incorporated into the Comirnaty biological product file, but that it expected to be better positioned to provide its best estimates at the time of the next joint status report.

FDA has produced 779,206 pages to date.

- **Plaintiff's Statement**: Plaintiff asserts that this volume exceeds the volume of approximately 450,000 pages it had long expected. Hence, on September 27, 2022, Plaintiff wrote to FDA about including in the then upcoming JSR "how many more pages of responsive documents the agency plans to produce," to which FDA did not provide an estimate. Plaintiff again asked for an estimate on December 22, 2022, as noted above. FDA has now finally provided an estimate, which reflects a completion date well past that expected by Plaintiff. As for FDA's claim below regarding what it advised in the earlier stages of this litigation related to estimated pages, the record speaks for itself.
- **Defendant's Statement**: FDA does not agree with Plaintiff's characterization of their September 27, 2022 communications. FDA acknowledges that the number of pages responsive to Plaintiff's FOIA request exceeds the preliminary estimates

provided by FDA at an earlier stage of the litigation but notes that, at the time, FDA made clear that there may be more responsive records than it had been able to account for thus far, including, *inter alia*, more unpaginated data files. Additionally, FDA has complied with the Court-ordered production schedule in this matter. At this time, FDA estimates that there are approximately 372,000 pages left to process. Based on that estimate and the pages FDA has banked to date, FDA estimates that it will complete production of responsive records in November 2023. FDA also notes that should it identify additional responsive records during the course of its continued review that would affect the anticipated completion date of November 2023, it will notify Plaintiff.

The parties intend to continue discussing the remaining production and the volume and timing for completion of same.

The parties will submit another joint status report within 90 days.

Dated: March 24, 2023

Respectfully submitted,

SIRI & GLIMSTAD LLP

/s/ Elizabeth A. Brehm
Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
200 Park Avenue
17th Floor
New York, New York 10166
Tel: (212) 532-1091
aaron@sirillp.com
ebrehm@sirillp.com

Attorneys for Plaintiff

BRIAN M. BOYNTON
Principal Deputy Assistant
Attorney General
Civil Division

ELIZABETH J. SHAPIRO
Deputy Director
Federal Programs Branch

/s/ Kevin Wynosky
KEVIN WYNOSKY
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs
Branch
1100 L Street NW
Washington, D.C. 20005
Tel: (202) 616-8267
Email: kevin.j.wynosky@usdoj.gov

Attorneys for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2023, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

/s/ Kevin Wynosky
KEVIN WYNOSKY
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch